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TOWNSEND and TOWNSEND and CREW LLP

By: /Brien M. Bergner/  
Brien M. Bergner

PATENT  
Attorney Docket No.: 082368-010000US  
Client Reference No.: EI-A0208P-US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Takeshi MATSUI et al.

Application No.: 10/591099

Filed: March 2, 2005

For: NOVEL GENE PARTICIPATING  
IN EPIDERMAL DIFFERENTIATION  
AND USE THEREOF

Confirmation No.: Not Yet Assigned

Examiner: Not Yet Assigned

Art Unit: Not Yet Assigned

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In compliance with the requirements of 37 CFR §1.98(a)(2), copies of references 0004-0027, 0029-0035, 0037, 0039-0040, 0042-0054 are enclosed. Copies of references 0001I-0003, 0028, 0036, 0038, and 004I are not provided since they were cited in the International Search Report, and as such, should have been provided directly by the WIPO under the exchange program between the USPTO, the EPO, and the JPO. A copy of the Search Report is enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

/Kevin Bastian/

Kevin Bastian  
Reg. No. 34,774

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 415-576-0200  
Fax: 415-576-0300  
KLB:bmb  
60977633 v1

Substitute for form 1449A&B/PTO				<b>Complete if Known</b>	
				<i>Application Number</i>	10/591099
				<i>Filing Date</i>	March 2, 2005
				<i>First Named Inventor</i>	Matsui, Takeshi
				<i>Art Unit</i>	
				<i>Examiner Name</i>	
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<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures	T <sup>5</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>				
	0001	WO	01/21658	A1	03-29-2001	Human Genome Sciences, Inc.	<input type="checkbox"/>
	0002	WO	02/008288	A2	01-31-2002	Genentech, Inc.	<input type="checkbox"/>
	0003	WO	02/068628	A1	09-06-2002	Human Genome Sciences, Inc.	<input type="checkbox"/>

<b>NON PATENT LITERATURE DOCUMENTS</b>						
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	0004	AHO, Sirpa, et al.; "cDNA Cloning, mRNA Expression, and Chromosomal Mapping of Human and Mouse Periplakin Genes," <u>Genomics</u> ; March 1, 1988; pp. 242-247; 48:2.				<input type="checkbox"/>
	0005	ASSELINEAU, D. and M. Pruneras; "Reconstruction of 'simplified' skin: control of fabrication," <u>British Journal of Dermatology</u> ; 1984; pp. 219-222; 111: Supplement 27.				<input type="checkbox"/>
	0006	BACKENDORF, Claude and Daniel Hohl; "A common origin for cornified envelope proteins?," <u>Nature Genetics</u> ; October 1992; p. 91; 2:2.				<input type="checkbox"/>
	0007	BELL, Eugene, et al.; "Living Tissue Formed in vitro and Accepted as Skin-Equivalent Tissue of Full Thickness," <u>Science</u> ; March 6, 1981; pp. 1052-1054; 211:4486.				<input type="checkbox"/>
	0008	BERNARD, François-Xavier, et al.; "Comparison of gene expression profiles in human keratinocyte mono-layer cultures, reconstituted epidermis and normal human skin; transcriptional effects of retinoid treatments in reconstituted human epidermis," <u>Experimental Dermatology</u> ; February 11, 2002; pp. 59-74; 11:1.				<input type="checkbox"/>
	0009	BONKOBARA, M., et al.; "Identification of novel genes for secreted and membrane-anchored proteins in human keratinocytes," <u>British Journal of Dermatology</u> ; April 2003; pp. 654-664; 148:4.				<input type="checkbox"/>

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	0010	CELIS, Julio E., et al.; "The human keratinocyte two-dimensional gel protein database (update 1995): Mapping components of signal transduction pathways;" <u>Electrophoresis</u> ; December 1995; pp. 2177-2240; 16:12.			<input type="checkbox"/>
	0011	CHAMPLIAUD, Marie-France, et al.; "cDNA Cloning and Characterization of Scielin, a LIM Domain Protein of the Keratinocyte Comifed Envelope;" <u>The Journal of Biological Chemistry</u> ; November 20, 1998; pp. 31547-31554; 273:47.			<input type="checkbox"/>
	0012	COLE, Jana, et al.; "Early gene expression profile of human skin to injury using high-density cDNA microarrays;" <u>Wound Repair and Regeneration</u> ; September-October 2001; pp. 360-370; 9:5.			<input type="checkbox"/>
	0013	DISEPIO, Daniel, et al.; "Identification and characterization of a retinoid-induced class II tumor suppressor/growth regulatory gene;" <u>Proceedings of the National Academy of Sciences of the United States of America</u> ; December 8, 1998; pp. 14811-14815; 95:25.			<input type="checkbox"/>
	0014	ECKERT, Richard L.; "Structure, Function, and Differentiation of the Keratinocyte;" <u>Physiological Reviews</u> ; October 1989; pp. 1316-1346; 69:4.			<input type="checkbox"/>
	0015	ECKERT, Richard L., et al.; "The Epidermal Keratinocyte as a Model for the Study of Gene Regulation and Cell Differentiation;" <u>Physiological Reviews</u> ; April 1997; pp. 397-424; 77:2.			<input type="checkbox"/>
	0016	FRANK, Stefan and Sabine Wemer; "The Human Homologue of the Yeast <i>CHL1</i> Gene Is a Novel Keratinocyte Growth Factor-regulated Gene;" <u>The Journal of Biological Chemistry</u> ; October 4, 1996; pp. 24337-24340; 271:40.			<input type="checkbox"/>
	0017	FRANK, Stefan, et al.; "The human homologue of a bovine non-selenium glutathione peroxidase is a novel keratinocyte growth factor-regulated gene;" <u>Oncogene</u> ; February 27, 1997; pp. 915-921; 14:8.			<input type="checkbox"/>
	0018	FUCHS, Elaine; "Keratins and the Skin;" <u>Annual Review of Cell Division and Biology</u> ; 1995; pp. 123-153; 11.			<input type="checkbox"/>
	0019	FUCHS, Elaine and Carolyn Byrne; "The epidermis: rising to the surface;" <u>Current Opinion in Genetics and Development</u> ; October 4, 1994; pp. 725-736; 4:5.			<input type="checkbox"/>
	0020	FUCHS, Elaine and Howard Green; "Changes in Keratin Gene Expression during Terminal Differentiation of the Keratinocyte;" <u>Cell</u> ; April 19, 1980; pp. 1033-1042; 19:4.			<input type="checkbox"/>
	0021	ISHIDA-YAMAMOTO, Akemi and Hajime Iizuka; "Structural organization of cornified cell envelopes and alterations in inherited skin disorders;" <u>Experimental Dermatology</u> ; February 1998; pp. 1-10; 7:1.			<input type="checkbox"/>

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	0022	JANSEN, Bastiaan J. J., et al.; "Serial Analysis of Gene Expression in Differentiated Cultures of Human Epidermal Keratinocytes;" <u>The Journal of Investigative Dermatology</u> ; January 2001; pp. 12-22; 116:1.			<input type="checkbox"/>
	0023	KALININ, Andrey E., et al.; "Assembly of the epidermal cornified cell envelope;" <u>Journal of Cell Science</u> ; September 2001; pp. 3069-3070; 114: Part 17.			<input type="checkbox"/>
	0024	KALININ, Andrey E., et al.; "Epithelial barrier function: assembly and structural features of the cornified cell envelope;" <u>BioEssays</u> ; September 2002; pp. 789-800; 24:9.			<input type="checkbox"/>
	0025	KATZ, Anne B. and Lorne B. Taichman; "A Partial Catalog of Proteins Secreted by Epidermal Keratinocytes in Culture;" <u>The Journal of Investigative Dermatology</u> ; May 1999; pp. 818-821; 112:5.			<input type="checkbox"/>
	0026	KAZEROUNIAN, Shideh and Sirpa Aho; "Characterization of Periphilin, a Widespread, Highly Insoluble Nuclear Protein and Potential Constituent of the Keratinocyte Cornified Envelope;" <u>The Journal of Biological Chemistry</u> ; September 19, 2003; pp. 36707-36717; 278:38.			<input type="checkbox"/>
	0027	KITA, Hiroko, et al.; "An Expression Profile of Active Genes in Cultured Human Keratinocytes;" <u>DNA Research</u> ; February 29, 1996; pp. 1-7; 3:1.			<input type="checkbox"/>
	0028	KOMIYA, Tohru, et al.; "A Large-Scale <i>in Situ</i> Hybridization System Using an Equalized cDNA Library; <u>Analytical Biochemistry</u> ; December 1, 1997; pp. 23-30; 254:1.			<input type="checkbox"/>
	0029	KONISHI, Keisuke, et al.; "Cataloguing of the Genes Expressed in Human Keratinocytes; Analysis of 607 Randomly Isolated cDNA Sequences;" <u>Biochemical and Biophysical Research Communications</u> ; July 29, 1984; pp. 976-983; 202:2.			<input type="checkbox"/>
	0030	KRIEG, Peter, et al.; "Repein ( <i>Rptn</i> ), a New Member of the 'Fused Gene' Subgroup within the S100 Gene Family Encoding a Murine Epidermal Differentiation Protein;" <u>Genomics</u> ; August 1, 1997; pp. 339-348; 43:3.			<input type="checkbox"/>
	0031	MÄÄTTÄ, Arto, et al.; "Structure and Regulation of the Envoplakin Gene;" <u>The Journal of Biological Chemistry</u> ; June 30, 2000; pp. 19857-19865; 275:26.			<input type="checkbox"/>
	0032	MACKENZIE, Ian C. and Norbert E. Fusenig; "Regeneration of Organized Epithelial Structure;" <u>The Journal of Investigative Dermatology</u> ; July 1983; pp. 189s-194s; 81: Supplement.			<input type="checkbox"/>

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	0033	MAKINO, Teruhiko, et al.; "Hornatin, a Novel Profilaggrin-like Protein and Differentiation-specific Marker Isolated from Mouse Skin;" <i>The Journal of Biological Chemistry</i> ; December 14, 2001; pp. 47445-47452; 276:50.			<input type="checkbox"/>
	0034	MARENHOLZ, Ingo, et al.; "Genetic Analysis of the Epidermal Differentiation Complex (EDC) on Human Chromosome 1q21: Chromosomal Orientation, New Markers, and a 6-Mb YAC Contig;" <i>Genomics</i> ; November 1, 1996; pp. 295-302; 37:3.			<input type="checkbox"/>
	0035	MARENHOLD, Ingo, et al.; "Identification of Human Epidermal Differentiation Complex (EDC)-Encoded Genes by Subtractive Hybridization of Entire YACs to a Gridded Keratinocyte cDNA Library;" <i>Genome Research</i> ; March 2001; pp. 341-355; 11:3.			<input type="checkbox"/>
	0036	MATSUI, Takeshi, et al.; "Identification of novel keratinocyte-secreted peptides dermokine- $\alpha$ -/ $\beta$ and a new stratified epithelium-secreted protein gene complex on human chromosome 19q13.1;" <i>Genomics</i> ; August 2004; pp. 384-397; 84:2.			<input type="checkbox"/>
	0037	MISCHKE, Dietmar, et al.; "Genes Encoding Structural Proteins of Epidermal Cornification and S100 Calcium-Binding Proteins Form a Gene Complex ('Epidermal Differentiation Complex') on Human Chromosome 1q21;" <i>The Journal of Investigative Dermatology</i> ; May 1996; pp. 989-992; 106:5.			<input type="checkbox"/>
	0038	MOFFATT, Pierre, et al.; "Identification of a conserved cluster of skin-specific genes encoding secreted proteins;" <i>Gene</i> ; June 9, 2004; pp. 123-131; 334.			<input type="checkbox"/>
	0039	MOLL, Roland, et al.; "Different Keratin Polypeptides in Epidermis and other Epithelia of Human Skin: A Specific Cytokeratin of Molecular Weight 46,000 in Epithelia of the Pilosebaceous Tract and Basal Cell Epitheliomas;" <i>The Journal of Cell Biology</i> ; October 1982; pp. 285-295; 95:1.			<input type="checkbox"/>
	0040	MUNZ, Barbara, et al.; "Differential Expression of the Calpastatin I Subunits Annexin II and p11 in Cultured Keratinocytes and During Wound Repair;" <i>The Journal of Investigative Dermatology</i> ; March 1997; pp. 307-312; 108:3.			<input type="checkbox"/>
	0041	OOMIZU, Souichi, et al.; "Kdap, a novel gene associated with the stratification of the epithelium;" <i>Gene</i> ; October 3, 2000; pp. 19-27; 256: 1-2.			<input type="checkbox"/>
	0042	PARENTEAU, Nancy L., et al.; "Epidermis Generated In Vitro: Practical Considerations and Applications;" <i>Journal of Cellular Biochemistry</i> ; March 1991; pp. 245-251; 45:3.			<input type="checkbox"/>
	0043	PARK, Geon Tae, et al.; "Suprabasin, a Novel Epidermal Differentiation Marker and Potential Cornified Envelope Precursor;" <i>The Journal of Biological Chemistry</i> ; November 22, 2002; pp. 45195-45202; 277:47.			<input type="checkbox"/>

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	0044	RIVAS, Miriam V., et al.; "Identification of Aberrantly Regulated Genes in Diseased Skin Using the cDNA Differential Display Technique;" <i>The Journal of Investigative Dermatology</i> ; February 1997; pp. 188-194; 108:2.			<input type="checkbox"/>
	0045	ROOP, Dennis; "Defects In the Barrier;" <i>Science</i> ; January 27, 1995; pp. 474-475; 267:5197.			<input type="checkbox"/>
	0046	ROTHNAGEL, Joseph A., et al.; "Characterization of the Mouse Loricrin Gene: Linkage with Profilagrin and the Flaky Tail and Soft Coat Mutant Loci on Chromosome 3;" <i>Genomics</i> ; September 15, 1994; pp. 450-456; 23:2.			<input type="checkbox"/>
	0047	van RUISEN, Fred, et al.; "A Partial Transcriptome of Human Epidermis;" <i>Genomics</i> ; May 2002; pp. 671-678; 79:5.			<input type="checkbox"/>
	0048	RUTBERG, Susan E., et al.; "Identification of Differentially Expressed Genes in chemically Induced Skin Tumors;" <i>Molecular Carcinogenesis</i> ; September 1997; pp. 88-98; 20:1.			<input type="checkbox"/>
	0049	SONG, Hae-Jun, et al.; "Mouse Spr2 Genes: A Clustered Family of Genes Showing Differential Expression in Epithelial Tissues;" <i>Genomics</i> ; January 1, 1999; pp. 28-42; 55:1.			<input type="checkbox"/>
	0050	STARK, Hans-Jürgen, et al.; "Organotypic Keratinocyte Cocultures in Defined Medium with Regular Epidermal Morphogenesis and Differentiation;" <i>The Journal of Investigative Dermatology</i> ; May 1999; pp. 681-691; 112:5.			<input type="checkbox"/>
	0051	TOULZA, Eve, et al.; "The Human Dermokine Gene: Description of Novel Isoforms with Different Tissue-Specific Expression and Subcellular Location;" <i>The Journal of Investigative Dermatology</i> ; February 2006; pp. 503-506; 126:2.			<input type="checkbox"/>
	0052	TRENKLE, Thomas, et al.; "Non-stoichiometric reduced complexity probes for cDNA arrays;" <i>Nucleic Acids Research</i> ; September 1, 1998; pp. 3883-3891; 26:17.			<input type="checkbox"/>
	0053	VOLZ, Armin, et al.; "Physical Mapping of a Functional Cluster of Epidermal Differentiation Genes on Chromosome 1q21;" <i>Genomics</i> ; October 1993; pp. 92-99; 18:1.			<input type="checkbox"/>
	0054	WATT, F. M.; "Terminal differentiation of epidermal keratinocytes;" <i>Current Opinion in Cell Biology</i> ; December 1989; pp. 1107-1115; 1:6.			<input type="checkbox"/>

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